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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/630,908

07/31/2003

Vigneswary Mala Ratnamohan

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07/05/2006

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,908	RATNAMOHAN ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/787,628.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0703:0904</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. It is noted that the instant application is a divisional of application no. 09/787,628, filed May 15, 2001, which is now U.S. Patent No. 6,627,418. The first line of the specification should be amended so as to provide the current status of the '628 application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-7 are indefinite over the recitation of the limitation "which method involves the use of a pair of oligonucleotide primers" in claim 4. The claims are drawn to a method "for amplifying HHV6 DNA," and this language does not make clear how "amplifying HHV6 DNA" is actually accomplished. For example, claim 4 refers to a "pair of oligonucleotide primers," but not make clear whether the claimed method requires the use of the recited molecules as a pair in an amplification reaction, or whether other manipulations involving the separate use of the primers would be encompassed by the claims. Clarification is required.

Claims 8 and 10-11 are indefinite over the recitation of the limitation "the HHV6 DNA...present in the sample" in claim 8, step (c), because there is insufficient antecedent basis for this limitation in the claims. While claim 8 previously refers to

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primers "complementary to and specific for HHV6 DNA," the claim does not previously refer to any HHV6 DNA in the sample employed in the claimed method.

Claims 8 and 10-11 are indefinite over the recitation of the step "detecting the amplified HHV6 DNA" in claim 8 (see step (d)). First, there is insufficient antecedent basis for the limitation "the amplified HHV6 DNA." Second, it is noted that the claim is drawn to a method of "detecting HHV6 in a sample suspected of containing HHV6" (not to a method of detecting amplified HHV6 DNA). This language does not apprise one of skill in the art as to how the detection of HHV6 in the sample is actually accomplished.

Claim 9 is indefinite over the recitation of each of the following limitations which lack sufficient antecedent basis in the claim: "the denatured single stranded DNA molecules" (see step (a)(iv)); "the region of DNA encoding the double stranded viral DNA" (see step (a)(vi)); "the optionally amplified sample" (see step (b)); "the optionally amplified double stranded viral DNA" (see step (c)); and "the region of DNA defined by the inner primers" (see step (e) – see also the recitation "the region of DNA" in step (f)).

Claims 9 is indefinite over the recitation of the step "detecting the amplified DNA" in step (g) of the claim. First, there is insufficient antecedent basis for the limitation "the amplified DNA." Second, it is noted that the claim is drawn to a method of "detecting HHV6 in a sample suspected of containing HHV6" (not to a method of detecting amplified DNA). This language does not apprise one of skill in the art as to how the detection of HHV6 in the sample is actually accomplished.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 8-11 rejected under 35 U.S.C. 102(b) as being clearly anticipated by McElhinney et al (Journal of Virological Methods 53(2,3):223-233 [1995]).

It is noted that step (a) of each of claims 8-9 is optional (see the recitation “optionally amplifying” at the beginning of step (a) in each of claims 8-9).

McElhinney et al disclose the PCR amplification of HHV6 DNA using primers H6-6 and H6-7, which primers are identical to instant SEQ ID Nos 3-4, respectively (see entire reference, particularly page 225). McElhinney et al disclose that their PCR comprises steps of combining PCR reagents and an “appropriate DNA sample,” followed by repeated cycles of denaturation, annealing, and extension to accomplish amplification (see pages 225-226). McElhinney et al further disclose a step of detecting amplification products (see page 226). McElhinney et al report that their method was used to detect “HHV-6 in urine specimens from an infant with exanthem subitum” (see page 231). McElhinney et al therefore teach a method meeting all the requirements of instant claims 8-11.

6. Claims 4-11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Secchiero et al (Journal of Infectious Diseases 171:273-280 [1995]).

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It is first noted that Applicants' specification defines a "functionally equivalent sequence" as "a sequence being different by one or more bases but still specific for and able to bind to the DNA of HHV6" (see page 2).

Secchiero et al disclose two different nested PCR assays that specifically amplify HHV6 DNA (see entire reference, particularly pages 274-275). It is noted that each of the inner and outer primer pairs of Secchiero et al are "functionally equivalent" to the primer pairs of the instant claims (see definition of "functionally equivalent" noted above). With further regard to claims 5-6, all of the primers of Secchiero et al meet the length requirements of the claims. With further regard to claim 7, the primer pairs of Secchiero consist of sequences that are functionally equivalent to SEQ ID NOS 1-2, as required by the claim. Regarding claims 8-11, Secchiero et al disclose steps of adding DNA samples to PCR reagents, followed by repeated cycles of denaturation, annealing, and extension, and subsequent detection of amplified DNA (see page 274). Further, Secchiero et al disclose performing their methods on serum samples, and disclose detecting HHV6 DNA in samples obtained from children with exanthema subitum, a CFS patient, HIV infected subjects, and bone marrow transplant recipients (see page 275-277, particularly Table 2). With further regard to claim 9, step (a)(ii), Secchiero et al disclose that the reagents employed in their reactions include PCR buffer, dNTPs, and thermostable polymerase (see page 274). Accordingly, Secchiero et al anticipate the claimed invention.

Drawings

7. The drawings are objected to because each of the drawings (Figures 1 and 2) contains text that too small to be clear and legible. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

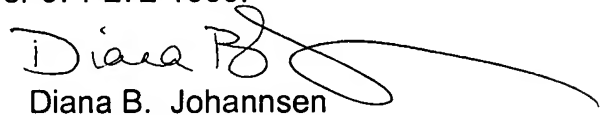
Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Diana B. Johannsen
Primary Examiner
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